

CoaguChek® XS PT Test

US REF 0 4625374160
6 Test Strips REF 0 4499603001
and 1 Code Chip
PERSONAL USE

Purpose

The CoaguChek XS PT test strips are part of the CoaguChek XS System. The CoaguChek XS System measures blood-clotting time for people who are taking anticoagulation medications such as Coumadin® or warfarin. The CoaguChek XS System uses blood from a fingerstick. The system is intended for properly selected and suitably trained users or their caregivers on the prescription or other order of the treating doctor. Users should be stabilized on anticoagulation medications such as Coumadin or warfarin prior to self-testing with the CoaguChek XS System.

Caution: These test strips are for use outside the body only. Do not eat the test strips.

Before You Start Testing

If you are new to the CoaguChek XS System, watch the *CoaguChek XS System Patient Training DVD* and read the *CoaguChek XS System Getting Started Guide* before testing.

Storing the Test Strips

Store the test strips in their container, with the cap closed. You can store the test strips at room temperature or in the refrigerator (2 to 30°C or 36 to 86°F). When stored properly, the test strips can be used until the expiration date printed on the test strip strip container.

Throw the test strips away if they are past their “Use By” date.

Handling the Test Strips

When you are ready to test, remove 1 test strip from the container. **Close the container tightly.**

You must use the test strip within 10 minutes of removing it from the container. Otherwise, you may get an error message and you will have to repeat the test.

Step 1: Getting Ready to Test

Gather supplies:

- CoaguChek XS Meter
- Container of CoaguChek XS PT Test Strips
- Test Strip Code Chip
- ACCU-CHEK® Softclix Lancet Device and Lancet



Place the meter on a flat surface (like a table or countertop) or hold it roughly horizontal so that it will not vibrate or move during testing. Vibrations or other movement can result in an error message.

If you are using test strips from a new, unopened box, you will need to change the test strip code chip. The 3-number code on the test strip container must match the 3-number code on the code chip. To install the code chip, follow the instructions in the *Code Chip* section of the *CoaguChek XS System User Manual for Self-Testing*.

Step 2: Getting a Good Drop of Blood

Increasing the blood flow in your finger will help you get a good drop of blood. Before you lance your finger, try the following techniques until you see that your fingertip has good color:

- Warm your hand by holding it under your arm, using a hand warmer, and/or washing your hand with warm water.
- Hold your arm down to the side so that your hand is below your waist.
- Massage your finger from its base.
- If needed, immediately after lancing, gently squeeze your finger from its base to encourage blood flow.

Step 3: Performing the Test

1. Wash your hands with warm, soapy water. Dry completely.

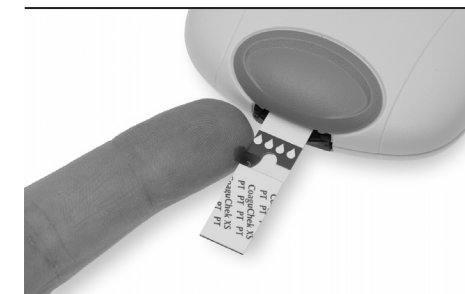


2. Take a test strip out of the container. **Close the container tightly.**
3. Insert a test strip as far as you can into the meter. The meter turns on.
4. Confirm that the number displayed matches the number on the test strip container, then press **M**. If the numbers are different, make sure you are using the code chip that came with the test strips you are using. If they still do not match, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.



5. An hourglass appears as the meter warms up, which takes about 30 seconds.
6. When the meter is warmed up, a flashing test strip and blood drop symbol appear and the meter begins a countdown. You have 120 seconds to apply blood to the test strip.

7. Use the lancet device to perform a fingerstick. **Set the penetration depth to 5.** See the *CoaguChek XS System User Manual for Self-Testing* for more information. After sticking your finger, you have 15 seconds to apply blood to the test strip. If it takes longer to form a good drop of blood, lance a different finger for the test.



8. Apply 1 drop of blood to the side of the test strip.

It's important to hold the blood drop to the test strip until you hear a beep.

9. You'll see the hourglass when the blood test begins. Then, pull your finger away from the test strip.



Remember to apply only one drop of blood—don't add more. Do not touch or remove the test strip when a test is in progress.

The result appears in about 1 minute.

10. Record the result on the *CoaguChek XS System Prothrombin Time Self-Testing Log Book*. Call your doctor with the test result.
11. Properly dispose of the used lancet and test strip.
12. Turn the meter off.

If you need to redo a test, use a new lancet, a new test strip, and a different finger.

Limitations of Procedure

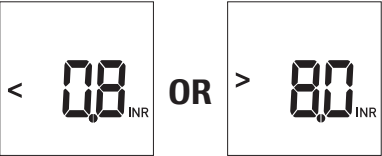
Information for You and Your Physician:

- The CoaguChek XS System for patient self-testing should not be used for patients being treated with any direct thrombin inhibitors, including Hirudin, Lepirudin, Bivalirudin and Argatroban.
- The CoaguChek XS PT Test for patient self-testing uses only fresh capillary blood from a fingerstick.
- The blood drop must be a minimum of 10 µL in volume. Low sample volume will cause an error message.
- Never add more blood to test strip after test has begun or perform another test using the same fingerstick.
- When a patient is on intravenous infusion therapy, do not collect fingerstick sample from arm receiving the infusion line.
- Hematocrit ranges between 25-55% do not significantly affect results.
- Testing has confirmed that PT/INR test results are *not* affected by:
- Bilirubin up to 30 mg/dL
- Lipemic samples containing up to 500 mg/dL of triglycerides.
- Hemolysis up to 1000 mg/dL
- Clopidogrel (Plavix®) up to 20 mg/dL
- Fondaparinux (Arixtra®) up to 5 mg/L
- The results are unaffected by heparin concentrations up to 0.8 U/mL.

- The CoaguChek XS PT Test is insensitive to low molecular weight heparins (LMWH) up to 2 IU anti-factor Xa activity/mL.
 - The presence of anti-phospholipid antibodies (APAs) such as Lupus antibodies (LA) can potentially lead to prolonged clotting times, i.e., elevated INR values. If you have or suspect that you have APAs, contact your doctor.
 - Differences in reagents, instruments, and pre-analytical variables can affect prothrombin time results. These factors should be considered when comparing results from different test methods. Results obtained with the CoaguChek XS System for patient self-testing may not consistently correlate with clinical laboratory results, particularly for certain types of laboratory reagents. Your doctor can provide additional information regarding results comparison.
 - In rare cases, patients with long clotting times (>8 INR) may receive an “ERROR 7” message on the meter display. If this error message appears again after repeating the test, call your doctor immediately to arrange for testing using another method.
- Additional Information**
The *CoaguChek XS System User Manual for Self-Testing* contains more information. If you need technical help, call the Roche Diagnostics Technical Service Center at 1-800-428-4674, 24 hours a day, 7 days a week, 365 days a year.

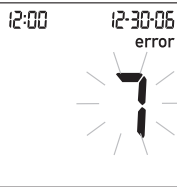
Very Low or Very High Test Results

The CoaguChek XS PT test strips provide test results if the INR value is between 0.8 and 8.0. If the meter displays < (less than) **0.8** or > (greater than) **8.0**, repeat the test. If, when you repeat the test, you get the same display (either < **0.8** or > **8.0**), call your doctor.



Error Messages

If you see Error 7, this means the meter was unable to detect a clot. Repeat the test. Be sure to carefully follow the steps in the *CoaguChek XS System User Manual for Self-Testing*. For example, make sure the fingertip is thoroughly dry, use the meter on a surface free of vibrations, and apply the blood drop within 15 seconds of sticking the fingertip. If you still get Error 7, call your doctor immediately to arrange for testing using another method. If the meter displays any other error message, refer to the *Error Messages* section of the *CoaguChek XS System User Manual for Self-Testing*.



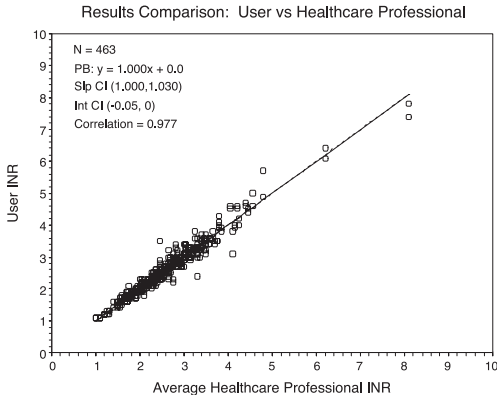
Built-In Controls

The CoaguChek XS System has built-in quality control functions in the meter and test strips. The meter automatically runs its own quality control test as part of every blood test, so you never have to run quality control tests with liquid quality controls. For more information about the built-in quality control functions, see the *CoaguChek XS System User Manual for Self-Testing*.

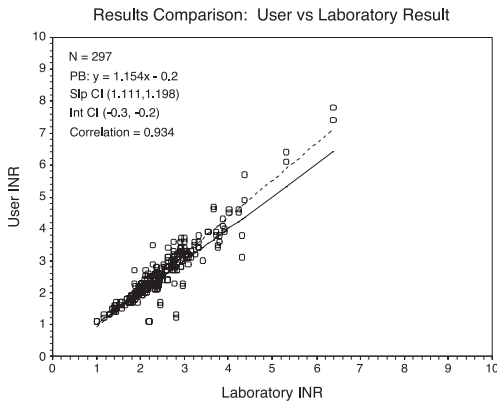
Performance Characteristics

Measuring Range: The CoaguChek XS PT System has a PT measuring range of 0.8–8.0 INR and 9.6–96.0 seconds.

Accuracy: A study was conducted comparing test results obtained by trained users with those obtained by healthcare professionals, when both were using the CoaguChek XS System. The correlation was very good, as indicated by the following statistics: N=463, Slope=1.000, Intercept=0.0 and Correlation Coefficient=0.977. This study shows that trained users are able to obtain results that are as accurate as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.



The test results obtained by trained users were also compared to results obtained using a laboratory-based reference method. Results are shown in the plot below.



Study User Demographics: A clinical study was conducted by Roche Diagnostics, consisting of four visits to the clinical site. Informed consent and randomization occurred at Visit 1. Testing began at Visit 2. Ninety-one patients completed at least one visit after Visit 1. The following table outlines the demographic information for the trained users who completed at least one visit after Visit 1.

Demographic	Number	Percent
Total number of users	91	100%
Caregivers	4	4.4%
Males	51	56%
Females	40	44%
Age range	32 – 89	100%
Mean Age	64 years	N/A
Age 65 – 69 years	16	17.6%
Age 70 – 74 years	13	14.3%
Age 75 years and up	16	17.6%
Education Level- Eighth grade or less through advanced college degree	91	100%
Median Education Level	Some college	N/A
On warfarin 3 – 12 months	19	20.9%
On warfarin 1 – 2 years	22	24.2%

On warfarin 3 – 5 years	23	25.3%
On warfarin > 5 years	27	29.7%
Atrial fibrillation	38	41.8%
Valve replacement	25	27.5%
Stroke/stroke prevention	7	7.7%
DVT	5	5.5%
Other heart conditions	6	6.6%
Other clotting disorders	10	11%

There were 107 patients enrolled. A total of 88 patients completed all four visits to the site. The reasons for drop-outs were as follows:

Reason for Drop-Out	# of Subjects
Felt it was too stressful	2
Didn't have time	3
Didn't want to use meter on his own	1
Didn't think he could learn to use meter	1
Was having knee surgery	1
Study terminated prior to Visit 4	1
Unknown	7
Disqualified due to target INR range outside of study protocol	3

Precision: A study was conducted and the precision of duplicates for capillary blood results was calculated for both trained users and healthcare professionals. The following results were obtained:

	User Results	Professional Results
N	214	249
Mean	2.57	2.52
SD	0.13	0.13
CV	5.13	5.36

This study shows that trained users are able to obtain results that are as precise as those obtained by healthcare professionals trained in the use of the CoaguChek XS System.

Limited Warranty

Roche Diagnostics warrants that your CoaguChek XS PT test strips will be free from defects in materials and workmanship until the product expiration date printed on the label if the test strips are stored and used in the manner described in this package insert and in your *CoaguChek XS System User Manual for Self-Testing*. If, prior to the expiration date of the test strips, there is a defect in materials or workmanship, Roche Diagnostics will replace the test strips free of charge. Your sole and exclusive remedy with respect to the strips shall be replacement. Any warranty claim should be directed to the Roche Diagnostics Technical Service Center at 1-800-428-4674.

THE ABOVE WARRANTY IS EXCLUSIVE OF ALL OTHER WARRANTIES, AND ROCHE DIAGNOSTICS MAKES NO OTHER WARRANTIES,

EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IN NO EVENT SHALL ROCHE DIAGNOSTICS BE LIABLE TO THE PURCHASER OR ANY OTHER PERSON FOR ANY INCIDENTAL, CONSEQUENTIAL, INDIRECT, SPECIAL OR PUNITIVE DAMAGES ARISING FROM OR IN ANY WAY CONNECTED WITH THE PURCHASE OR USE OF THE TEST STRIPS. NO WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, IF ANY IS IMPLIED FOR THE SALE OF THE TEST STRIPS, SHALL EXTEND FOR A LONGER DURATION THAN THE EXPIRATION DATE OF THE TEST STRIPS.

Aspects of the CoaguChek XS System (meter and test strips) and its use are covered by one or more of the following U.S. Patents: 6,662,439; 7,073,246; 6,881,378; 6,207,000; 7,084,251; 7,049,131; 5,625,036; 6,645,368. Additional U.S. Patents pending.

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